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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/450,609	11/30/1999	HELLE WEIBEL	DRF 3.0-051	7926
70554	7590	10/18/2007	EXAMINER	
Reddy Us Therapeutics, Inc 3065 Northwoods Circle Norcross, GA 30071			KIM, JENNIFER M	
		ART UNIT	PAPER NUMBER	
		1617		
		MAIL DATE	DELIVERY MODE	
		10/18/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/450,609	WEIBEL ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 03 August 2007.  
 2a) This action is **FINAL**.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 6,7,9,13,16 and 28-31 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 6,7,9,13,16 and 28 is/are rejected.  
 7) Claim(s) 29-31 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

## DETAILED ACTION

The response filed August 3, 2007 have been received and entered into the application.

### Action Summary

The objection to claims 6, 7, 9, 11-13, 16, 28-31 because of the minor informalities is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 6, 7, 9, 11-13, 16 and 28-31 under 35 U.S.C. 112, second paragraph is hereby expressly withdrawn in view of Applicants' amendment.

The rejection of claims 6, 7, 9, 11, 12, 13, 16, and 28 under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (WO 9741097) in view of Staniforth et al. (U.S. Patent No. 6,866,867 B2) and further in view of Van Leverink (U.S. Patent No. 4,280,997) is being maintained for the reasons stated in the previous Office Action.

The rejection of claims 6, 7, 9, 11-13, 16 and 28-31 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/699043 is hereby expressly withdrawn in view of the Terminal Disclaimer filed by Applicants.

The rejection of claims 6, 7, 9, 11-13, 16 and 28-31 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-18 of U.S.

Patent No. 6,710,050 is hereby expressly withdrawn in view of the Terminal Disclaimer filed by Applicants.

***Response to Arguments***

Applicants' arguments filed August 3, 2007 have been fully considered but they are not persuasive. Applicants argue that Van Leverink teaches away from adding water and after-drying can cause "unacceptable hygroscopic properties" for anhydrous lactose. Applicants argue that Staniforth, in contrast to Van Leverink, discloses that the microcrystalline cellulose is accomplished by preparing aqueous slurry. and drying the mixture in a manner which reduces undesirable hydrogen bonding. This is not found persuasive because Lohray et al. teaches that the active agent, **5-[[4-3-Methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-methyl]thiazolidine-2,4-dione** can be formulated by **compression by tabletting machine** comprising excipients such as magnesium stearate, lactose, carboxymethyl cellulose, corn starch, flavourants, sweeteners and other media normally employed in preparing such composition. Staniforth et al. was cited by the Examiner only to show that microcrystalline cellulose has been utilized extensively in the pharmaceutical industry as a direct compression in forming solid dosage forms and that it has advantages compared to other directly compressible excipients by exhibiting superior compressibility and disintegration properties. Likewise, Van Leverink was cited by the Examiner to show that anhydrous lactose is very suitable as diluents in tablet manufacturing that its use is important

because that the presence of moisture in any form in tablets have negative influence upon the quality of the tablets because of the reaction of water with the active ingredients in tablet. Therefore, it would have been obvious to one of ordinary skill in the art to modify Lohray tablet composition comprising lactose in general, and employ anhydrous lactose in view of what is generally known in manufacturing tablets in pharmaceutical industry, that the presence of moisture in any form in tablet have a negative influence upon the quality of the tablet due to the reaction of water with the active ingredient, as reported by Van Leverink. Further, it would have been obvious to modify the Lohray's tablet composition to employ microcrystalline cellulose by direct compression in formulating the tablet because microcrystalline cellulose has beneficial use in solid dosage forms because of its superior compressibility and disintegration property in view of Staniforth et al. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6, 7, 9, 11, 13, 16, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lohray et al. (WO 9741097) of record in view of Staniforth et al. (U.S. Patent No. 6,866,867 B2) and further in view of Van Leverink (U.S. Patent No. 4,280,997).

Lohray et al. at page 34, lines 27-29, page 35, example, and page 7, lines 13-14, teach pharmaceutical composition comprising applicants' active agent, **5-[[4-3-Methyl-4-oxo-3,4-dihydro-2-quinazolinyl]methoxy]phenyl-methyl]thiazolidine-2,4-dione**, can be formulated in **tablet, capsule, or powder form** (dry form), and can be combined with the pharmaceutically acceptable excipient such as **magnesium stearate, lactose, carboxymethyl cellulose, corn starch, flavourants, sweeteners**, and other media normally employed in preparing such compositions. Lohray et al. teach that the above composition typically contains from 1 to 20% by weight of active compound, and the remainder of the composition being pharmaceutically acceptable carrier, diluents or solvents. (page 35, lines 1-3).

Lohray et al. do not expressly teach the composition as being **low water content** comprising **anhydrous lactose** and **microcrystalline cellulose** and proportions of excipients set forth in claim 9 and formulating tablet by **direct compression** set forth in claim 28.

Van Leverink teaches that it is known that **anhydrous lactose** is very suitable as diluents in tablets. (column 1, lines 33-35). Van Leverink reports that when manufacturing tablets and capsules in pharmaceutical industry, the use of the **lactose** is important and it is generally known that the presence of **moisture** in any form in tablets

capsules may have a negative influence upon the quality of the tablets for capsules because the **water reacts** with the active ingredient in the tablet or the capsules. (column 1, lines 12-15).

Staniforth et al. teach that **microcrystalline cellulose** has been utilized extensively in the pharmaceutical industry as a **direct compression** vehicle for **solid dosage forms**. Staniforth et al. teach that **microcrystalline cellulose** is commercially available and compared to other **directly compressible** excipients, it is generally considered to **exhibit superior** compressibility and disintegration properties. (column 2, lines 44-53).

It would have been obvious to one of ordinary skill in the art to modify Lohray tablet composition comprising lactose in general, and employ anhydrous lactose because it is known that anhydrous lactose is very suitable as a diluents in tablet because it is generally known that when manufacturing tablets in pharmaceutical industry, that the presence of moisture in any form in tablet have a negative influence upon the quality of the tablet due the water reacting with the active ingredients as well known by Van Leverink. One would have been motivated to employ anhydrous lactose to obtain very low content of water of Lohray's tablet composition in order to achieve a quality tablet formulation lack moisture in order to avoid the negative influence upon the quality of the tablets well known by Van Leverink.

It would have been obvious to modify the Lohray's tablet composition to employ microcrystalline cellulose by direct compression in formulating the tablet because Staniforth et al. teach that microcrystalline cellulose is generally considered to exhibit

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superior compressibility and disintegration property and it was been utilized extensively in the pharmaceutical industry to formulate solid dosage forms. One would have been motivated to employ microcrystalline cellulose in Lohray's composition in order to achieve an expected benefit of having superior disintegration properties of tablet formulated with superior compressibility with known direct compression technique. The proportions of active agents to be used set forth in claim 9 is deemed obvious because it is within the knowledge of the skilled pharmacologist to optimize the range of amounts of active agents and the excipients to be utilized. Moreover, Lohray et al. teach the ranges of 1-20% as being an active compound and the remainder of the composition being pharmaceutically acceptable carriers, diluents or solvents. One of ordinary skill in the art would optimize this range of excipients within the range of about 20-80% as taught by Lohray et al.

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 103.

#### ***Allowable Subject Matter***

Claims 29-31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Jennifer Kim  
Primary Examiner  
Art Unit 1617

Jmk  
October 15, 2007